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| 09/874,308 | 06/06/2001 | Takeshi Fujita | 381NT/42535D2 | 8142 |

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,308

Applicant(s)

FUJITA ET AL.

Examiner

Frank W Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/552,496.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1634

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on December 30, 2002 has been entered. The claims pending in this application are claims 50-59. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment

Claim Objections

2. Claim 50 is objected to because of the following informalities: (1) the phrase "intercalating an intercalater capable of emitting fluorescence of an given wavelength upon receiving an excitation beam of another given wavelength" should be "intercalating an intercalater capable of emitting fluorescence **in** an given wavelength upon receiving an excitation beam **in** another given wavelength"; (2) the word "conformation" in line 6 should be "**a** conformation"; (3) "irradiating the excitation beam of the given wavelength" should be "irradiating the excitation beam **in** the given wavelength"; and (4) "an intensity of the fluorescence of a present wavelength" should be "an intensity of the fluorescence **in the** present wavelength".
3. Claim 51 is objected to because of the following informality: "the least statistical error" should be "least statistical error".
4. Claim 52 is objected to because of the following informality: "the least statistical error" should be "least statistical error".
5. Claim 59 is objected to because of the following informality: "the least statistical error" should be "least statistical error".

Art Unit: 1634

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 50-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claims 51-59 are dependent on claim 50.

8. Claim 50 is rejected as vague and indefinite in view of the phrase "intercalating an intercalater capable of emitting fluorescence of an given wavelength upon receiving an excitation beam of another given wavelength when it is intercalated with the base paring nucleotides from conformation of the sample single-stranded DNA fragment in the sample solution" because it is unclear whether the word "it" in this phrase means an intercalater or not. If the word "it" means an intercalater, it appears that "intercalating an intercalater" and "it is intercalated with the base paring nucleotides from conformation of the sample single-stranded DNA fragment in the sample solution" in this phrase are directed to two identical method steps. Since, from the dictionary, the word "intercalate" means "insert, interpolate, or interpose", the examiner suggests that applicant change the phrase "when it is intercalated with the base paring nucleotides from conformation of the sample single-stranded DNA fragment in the sample solution" to "when the intercalater is interacted with the base paring nucleotides from a conformation of the sample single-stranded DNA fragment in the sample solution" in order to overcome the rejection.

Art Unit: 1634

9. Claim 50 is rejected as vague and indefinite because it is unclear what kind of denaturing condition can be considered as a given denaturing condition since it is known that only heat denaturation of single stranded DNA fragment generates a melting curve while the claim is directed to any kind of given denaturation condition. Please clarify.

10. Claim 50 is rejected as vague and indefinite in view of the phrase "for analyzing for a DNA polymorphism including a single-base substitution in the sample single-stranded DNA fragment" because it is unclear what it intended. For example, since "including" is equivalent to the phrase "such as", it is unclear whether the claim is limited to a single-base polymorphism or not? Please clarify. Note that the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. Claim 51 is rejected as vague and indefinite in view of phrase "comparing the measured melting curve data of the sample single-stranded DNA fragment with a data set of known melting curves or with a data set of curves prepared by linear combination of a plurality of known curve data sets, and determining that a data set of known melting curve with the least statistical error compared to the measured melting curve data or a linear combination of data sets with the least statistical error compared to the measured melting curve data represents sequence information of the sample single-stranded DNA fragment" because it is unclear whether "a data set of known melting curves" in "comparing" step and "a data set of known melting curves" in "determining" step are directed to the same thing or not. If "a data set of known melting curves" in two method steps are directed to the same thing, "a data set of known melting curves" in "determining" step

Art Unit: 1634

should be “the data set of known melting curves”. Furthermore, it is unclear that “a data set of curves prepared by linear combination of a plurality of known curve data sets” in “comparing” step and “a linear combination of data sets” in “determining” step are directed to the same thing or not. If “a data set of curves prepared by linear combination of a plurality of known curve data sets” in “comparing” step and “a linear combination of data sets” in “determining” step are directed to the same thing, “a linear combination of data sets” in “determining” step should be “the linear combination of data sets”. Please clarify.

12. Claim 51 is rejected as vague and indefinite because it is unclear how the measured melting curve data is correlated with the sequence information of the sample single-stranded DNA fragment. It is known that a melting curve is correlated with heat denaturation of nucleic acid and is not correlated with the sequence information of a nucleic acid. Please clarify.

13. Claim 52 is rejected as vague and indefinite because it is unclear whether “known melting curves” in “calculating” step and “selecting” step are directed to the same thing or not. If “known melting curves” in “calculating” step and “selecting” step are directed to the same thing, “known melting curves” in “selecting” step should be “the known melting curves”. Furthermore, it is unclear “a data set of curves prepared by linear combination of a plurality of known melting curve data sets” in “calculating” step and “selecting” step are directed to the same thing or not. If “a data set of curves prepared by linear combination of a plurality of known melting curve data sets” in “calculating” step and “selecting” step are directed to the same thing, “a data set of curves prepared by linear combination of a plurality of known melting curve data sets” in “selecting”

Art Unit: 1634

step should be "the data set of curves prepared by linear combination of a plurality of known melting curve data sets". Please clarify.

14. Claim 52 is rejected as vague and indefinite in view of phrase "provide curve data sets in order of increasing statistical error as the sequence information of the measured sample single-stranded DNA fragment" because it is unclear how melting curve is correlated with the sequence information of a nucleic acid since it is known that a melting curve is correlated with heat denaturation of nucleic acid and is not correlated with the sequence information of a nucleic acid. Please clarify.

15. Claim 59 is rejected as vague and indefinite in view of phrase "defining as the sequence information of the sample single-stranded DNA fragment as a known melting curve data set" because it is unclear how the sequence information can be defined as a known melting curve data set since it is known that a melting curve is correlated with heat denaturation of nucleic acid and is not correlated with the sequence information of a nucleic acid. Please clarify.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1634

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. No claim is allowed.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Application/Control Number: 09/874,308

Page 8

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
March 12, 2003

A handwritten signature in black ink, appearing to read 'E. Whisenant', is positioned above the printed name.

Ethan Whisenant, Ph.D.
Primary Examiner (FSA)